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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,674

02/17/2006

Kristine G. Koski

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01/27/2010

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CANADA

EXAMINER

ROY, BAISAKHI

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

01/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,674	Applicant(s) KOSKI ET AL.	
	Examiner BAISAKHI ROY	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-17, 20, 21, 23-30, 32-34, 36, 38-40, 42-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 13-15 and 42 is/are allowed.
- 6) ☒ Claim(s) 16, 17, 20, 21, 23, 27-30, 32-34, 43- 46 is/are rejected.
- 7) ☒ Claim(s) 24-26, 36, 38-40 and 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 16, 17, 20, 21, 23, 27-30, 32-34, and 43-46 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

2. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-10, 13-15, and 42 are allowed. The prior art of record does not teach an *in situ* method of analyzing amniotic fluid using a *spectrometer* to acquire a spectrum to predict the risk of developing a medical condition in the pregnant mother or the offspring based on a predetermined correlation between spectra of amniotic fluid and the likelihood of developing the medical condition.

Claim Objections

3. Claims 24-26, 36, 38-40, and 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 16, 17, 23, 27-30, 43, 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarez (5856196). Alvarez discloses an apparatus and

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method for screening amniotic fluid by obtaining a spectrum of amniotic fluid (fig. 7, 8) by infrared spectroscopy (example 5). Alvarez does not explicitly teach of a medical condition such as high or low birth weight but it would be obvious to one of ordinary skill in the art that the screening of amniotic fluid would allow one to test for conditions such as high or low birth weight.

6. Claims 20, 32, 33, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarez in view of Khoury et al.

Alvarez does not teach the use of a Raman spectrometer. In the same field of endeavor Khoury et al. disclose a system and method for analysis of biological fluids including amniotic fluids (col. 2 lines 16-19). Khoury et al. also teach the use of a Raman spectrometer (col. 2 lines 46-49). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Khoury et al. to modify Alvarez such that the markers in the amniotic fluid flowing through the abdominal wall are analyzed in a fast and efficient manner for the recognition of materials or compounds that are indicative of birth disorders.

9. Claims 21 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarez in view of Ebbels et al.

Alvarez teaches the use of spectroscopy to analyze the markers in amniotic fluid but do not teach the use of magnetic resonance spectroscopy. In the same field of endeavor Ebbels et al. disclose a system and method for analyzing fluid samples including amniotic fluid using spectroscopy such as magnetic resonance spectroscopy (col. 12 lines 62-col. 13 line 9, lines 58-64). It would have therefore been obvious to

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one of ordinary skill in the art to use the teaching by Ebbels et al. to modify Alvarez such that significant markers/analytes found in amniotic fluid may be measured for effective diagnosis of birth disorders or abnormalities.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

BR

/B. R./
Examiner, Art Unit 3737